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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/061,025	01/30/2002	Morton J. Seligman	078061-31851	7891

26345 7590 04/07/2004

GIBBONS, DEL DEO, DOLAN, GRIFFINGER & VECCHIONE  
1 RIVERFRONT PLAZA  
NEWARK, NJ 07102-5497

EXAMINER
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HAGHIGHATIAN, MINA

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 04/07/2004

10

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/061,025

Applicant(s)

SELIGMAN, MORTON J.

Examiner

Mina Haghighatian

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 01 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of claims 1-20 under 35 U.S.C. 102(e) as being anticipated by Osbakken et al (20020061281 A1) is maintained.

Osbakken' reference was discussed in the Office Action mailed 12/18/02.

***Response to Arguments and Declaration***

Applicant's arguments and declaration filed 04/01/03 have been fully considered but they are not persuasive.

Applicant argues that Osbakken does not disclose treating the claimed disease, allergic fungal sinusitis and liquid montelukast delivered intranasally. This is not found persuasive because Osbakken discloses a teaching on treating sinusitis and refers to both infectious and allergic sinusitis. Osbakken discloses treating infectious fungal sinusitis with antibiotics and antifungal agents (Note [0117] and [0123]) and allergic fungal sinusitis with anti-leukotrienes such as montelukast and pranleukast (Note [0041], [0125] and [0126]). Osbakken is clearly disclosing that these medications (anti-leukotrienes) applied topically will reduce inflammation in the nasal cavity and thereby help prevent the development of and also shrink existing polyps.

Applicant argues that Osbakken is teaching administration of agents through an extranasal cloud mist by means of an aerosol nebulizer and not intranasally by a nose

spray. This is found not persuasive. Osbakken is teaching nebulizers as one embodiment of his invention. Nasal delivery is also taught and disclosed in various embodiments (Note [0053], [0070] and [0081]).

Applicant argues that Osbakken does not disclose the claimed daily dosage for montelukast. Applicant is referring to a filter test done on 3.5 mg dose as disclosed by Osbakken compared to a filter test on a lower dose, e.g. 2.5 mg, as disclosed by the claimed invention. This is not persuasive because the claimed daily dosage is from 0.03 to 10 mg and the disclosed 0.5 to 15 mg and in particular the 3.5mg dose of Osbakken meets the limitation. Also the claimed composition contains a liquid carrier such as saline. In comparison it is disclosed that Osbakken's solutions contain NACL ([0073]) and exemplified is a formulation containing 3.5 mg of montelukast in sterile water for injection ([0188]). According to MPEP, if the composition is physically the same, it must have the same properties (See MPEP 2112.01).

Applicant asserts that Osbakken is teaching away from intranasal administration, citing section [0020] of the patent publication. This is not correct. In section [0020] Osbakken is discussing effects of nasal decongestants in any one of spray, drops or vapor form. The said disclosure is not teaching away from intranasal administration. In section [0053] Osbakken discloses Wenig et al's reference which teaches that "nasal delivery provides enhanced bioavailability, minimized variations in blood levels, and more rapid onset of activity and reduced dosages as compared to administration such as oral or subcutaneous". The drawback of Wenig's teaching according to Osbakken is that Wenig does not disclose effective particle size for nasal sprays.

Thus it is the examiner's legal position that all the limitations of the instant claims are taught and disclosed by Osbakken.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 571-272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mina Haghighatian  
March 29, 2004

  
THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600